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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,672	04/02/2004	Fredrik Nicklasson	PC 27890A	9694

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
12/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@woodcock.com

Office Action Summary	Application No.	Applicant(s)	
	10/816,672	NICKLASSON ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-13 are pending in the application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

It is noted that the previous rejection only included claims 1-12. Claim 13 was improperly placed on the remarks page of the amendment dated 10/27/06 and therefore, the Examiner overlooked this pending claim. In all fairness to the Applicant, this case is non-final because claim 13 was not previously considered on its merits.

Applicant's arguments pertaining solely to the previous rejections are moot in light of the removal of those rejections. Applicant's amendments to the claims facilitated the new rejections found *infra* and have overcome the previous rejections under 35 USC 102(b) and 102(e) as well as the rejection under 35 USC 103(a) over Girsh (US 5,753,296) in view of Lapidus (US 4,937,076).

Claim Objections

Claim 1 is objected to because of the following informalities: Claim 1 recites 'bupropione.' The proper spelling of this drug is 'bupropion.'

Appropriate correction is required.

Election/Restrictions

Applicant's election with traverse of the species of bupropione in the reply filed on 10/09/2007 is acknowledged. The traversal is on the ground(s) that "the species are linked by generic claims." This is not found persuasive because the Examiner cannot quite understand this reasoning. Claim 1 is not a generic claim, it is a Markush claim and all other claims; i.e., claims 2-13 depend directly or indirectly upon claim 1. Because Applicant has not provided any evidence to support a contention that the claimed species are obvious variants, the requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruff et al. (5,731,000) view of Girsh (US 5,753,296) in view of Lapidus (US 4,937,076) in view of Patel et al. (US 2003/0215496).

Ruff et al. (US 5,731,000) taught that bupropion was a well-known anti-depressant, more recognized by the name of Wellbutrin ® (see entire reference, especially Col. 1 – Background). Ruff et al. specifically proposed sublingual dosage forms including lozenges which included bupropion hydrochloride as the active ingredient:

> Compositions suitable for topical administration in the mouth, for example bucally or sublingually, include lozenges comprising bupropion hydrochloride and the stabilizer in a flavored basis such as sucrose and acacia or tragacanth, and pastilles comprising the active compound in a basis such as gelatin and glycerin or sucrose and acacia.... In addition to the aforementioned ingredients, the compositions of this invention may further include one or more accessory ingredient(s) selected as appropriate from diluents, buffers, flavouring agents, binders, disintegrants, surface active agents, thickeners, lubricants, preservatives (including antioxidants) and the like (col.3, lines 39-44)

Ruff et al. did not however, specifically teach wherein the pharmaceutical composition contained a lipid such as cocoa butter or cocoa butter equivalents, wherein

the buffering agent was a buffering agent as listed in claim 6, wherein the thickening/binding agent was specifically an emulsifier such as lecithin or a taste modifier such as sodium chloride, or a coloring agent such as iron oxides, titanium dioxide or aluminum lakes.

Girsh (US 5,753,296) taught chocolate compositions containing hypoallergenic cocoa powder which advantageously included pharmaceutical agents for sublingual/mucosal delivery (see entire reference especially col.2, lines 61-67, col. 14, lines 3-52). In a specific embodiment, Girsh prepares a 'High phosphatidylcholine lecithin, sugar-free, chocolate flavored aspirin' in Example XXVII (col. 28) which comprised aspirin, hypoallergenic cocoa powder, lecithin, vanilla, cocoa butter and maltitol, formed into small units to be "...utilized as a pleasant tasting, high mucosal penetrating and oral absorbable delivery system which is maintained sublingually in the mouth until completely dissolved".

Girsh specifically explains that

> The inventive chocolate composition may be utilized as a vehicle for delivery of oral medications to **mask drug flavor** and provide for enhanced drug uptake via the oral mucosa. For example, a dosage form may be prepared by coating a medicament with a chocolate coating according to the present invention, or by mixing the medicament in a liquid or powder form with the chocolate composition. A chewable tablet, e.g., aspirin tablet, may thus be formed. The drug may comprise any pharmaceutical suitable for oral delivery, in particular those drugs such as

> dihydroergotamine...which are difficult to deliver by the oral route on account of poor absorption... (see col. 14, lines 17-28 – emphasis added).

Lapidus (US 4,937,076) disclosed a chewable aspirin tablet containing, *inter alia*, chocolate, aspirin and calcium carbonate (see entire reference, especially Abstract and col's 3-4). Lapidus explained that the buffering component present in the aspirin-containing chewable tablet advantageously contained a buffer in order to reduce gastric anomalies caused by the aspirin (see col. 1). Lapidus suggested the use of many suitable buffering components, including sodium carbonate (see Col. 3, line 59- col. 4, line 11.

Patel et al. (US 2003/0215496) taught that colorants such as lakes, iron oxides and titanium dioxide were well-known to be used in the pharmaceutical compounding industry (see for example, [0152]). Patel et al. additionally disclosed that buffers such as bicarbonates were well-known to be used in pharmaceutical compounding (see [0149]). Also see where Patel et al. specifically disclosed compounding bupropion with such agents ([0036]).

One of ordinary skill in the art would have been motivated to pharmaceutically modify the well-known agent bupropion into the claimed forms because these forms, including all of the limitations of the claims were already known in the art and considered routine in the art of pharmaceutical compounding. For example, one of

ordinary skill in the art would have been motivated to add cocoa powder to a pharmaceutical composition comprising bupropione in order to enhance the flavor of the pharmaceutical. Since Girsh already taught an advantageous medicinal lozenge composition of Example XXVII, one of ordinary skill in the art would have been motivated to substitute bupropion for the active ingredient of Girsh, since the example of Girsh would have been suitable for sublingual delivery of any known oral pharmaceutical agent which was known to have the ability to traverse the oral mucosa. Again, the oral composition of Girsh (Example XXVII) was a 'High phosphatidylcholine lecithin, sugar-free, chocolate flavored aspirin' (col. 28) which comprised aspirin, hypoallergenic cocoa powder, lecithin, vanilla and cocoa butter. Thus, one of ordinary skill in the art would have had a reasonable expectation that the lozenge of Girsh would have been suitable for delivering an active agent of bupropion.

One of ordinary skill in the art would have been motivated to add a buffer such as sodium carbonate to an oral dosage form comprising the claimed ingredients in order to balance and stabilize the pH of the composition. One of ordinary skill in the art would have been motivated to use sodium chloride in order to impart additional flavor to the oral composition. It was clear from Girsh that salt was used as a flavorant in the chocolate containing compositions (see Example XV); and it is also well known that salt is a flavoring agent. Therefore, one of ordinary skill in the art would have had a reasonable expectation that the addition of salt to the chocolate-aspirin composition of

Girsh would have provided for a more favorable product. "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton *KSR* 127S. Ct. at 1742.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention because cocoa powder containing vehicles were known in the art for the preparations of sublingual/transmucosal delivery of active agents. It is clear from the prior art that substances such as lecithins, cocoa butter, oils such as soybean oil, sweeteners and flavoring agents are routinely added to confectionary-type carriers containing chocolate/cocoa powder and that these types of carriers enhanced introral uptake of pharmaceutical agents. The addition of known, conventional additives to the composition does not render the composition patentable, because as stated *supra*, these compounds were routinely used in chocolate containing compositions and do not appear to impart any unexpected results to the composition. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The Supreme court has acknowledged that:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable varition..103 likely bars its patentability**...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's

> skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...
>
> ...**the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results** (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith

Primary Examiner
Art Unit 1655

December 11, 2007